

## REMARKS

Claims 1-29 and 34-36 are presently pending in the application.

### **I. Office Action Impropriety -- No Treatment of Claim Limitations**

The Final Office Action is improper and should be reissued, since, for example, the Final Office Action did not treat, or even address, the substantive, positively-claimed limitations of many and indeed most of the claims. As a consequence of not addressing important limitations, the Final Office Action is inappropriate, improper, fatally erred, and in need of being withdrawn. Each of the pending claims is a method claim. The Final Office Action did not appear to recognize the existence of the below process limitations, which are: (1) clearly recited in the pre-existing claims; (2) not in the cited prior art; (3) argued in Applicants' prior Amendment; and (4) not addressed in the Final Office Action's response to Applicants' arguments:

- a. "applying...material...to thereby cover *substantially all* exposed surfaces of the implant" (claim 1);
- b. "applying...material...around the implant...wherein...comprises...an edge *which is thicker*" (claim 1);
- c. "*applying the implant and...membrane* to...a region...susceptible to adhesions" (claim 1);
- d. "*applying...and attenuating...adhesions...at the region* within the human patient" (claim 1);
- e. "applying...and attenuating...wherein...membrane...comprises a *single layer*" (claim 2);
- f. "applying...and attenuating...wherein...the edge is *2 to 4 times thicker*" (claims 2-6, 14, 19, 21, 34, 36);
- g. "wherein...the step of applying...comprises *heat-shrinking*...around the implant" (claim 6); and
- h. "wherein the step of applying...comprises: *dissolving a polymer*...and coating" (claims 7-13).

Each of the above items must be addressed by the Examiner. Applicants previously made the above distinctions, but the Final Office Action did not even acknowledge them.

According to the Manual of Patent Examining Procedure (MPEP) Section 707.07(g), every issue that stands between the Applicants and allowance of the application needs to be identified by the Examiner, by clearly and crisply presenting the best case against patentability. (See, for example, MPEP Sections 2164.04 and 2106(II) “it is essential...complete examination...[u]nder the principles of compact prosecution...state all reasons and bases for rejecting claims”). In theory, this provides the Applicants with the opportunity to respond to each issue so that, if each issue is successfully rebutted or otherwise addressed, the application would be in condition for allowance. Conversely, if the Applicants are not successful, the application is in better condition for appeal. A failure to provide the best case such that a new rejection, new art, and/or expanded arguments are required in a subsequent Office Action generally precludes the finality of that subsequent Office Action. (See MPEP Section 706.07(a).) In practice, this prevents piecemeal prosecution of the application, which the MPEP instructs should be avoided. (See MPEP Section 707.07(g).)

## **II. Office Action Impropriety -- No Provision of Motivation-To-Combine**

No motivation to combine was provided on page 7 of the Final Office Action. The only content on the topic states “[i]t would have been obvious...to combine...to use the barrier sheet of Massie et al. in device of Bakker et al. in order to provide an anti-adhesive implant for use in back surgery.” This content is devoid of any motivation, whatsoever.

As a general principal, it is the Applicants, rather than the Examiner, who should be regarded as the relevant audience for the undertaking of an analysis on the sufficiency of the clarity of a reasoned rejection being applied against the Applicants. In the present situation, it is believed that not even a skilled patent practitioner can be expected to understand the Examiner’s silence on how one skilled in the art would have been motivated to combine the various alleged teachings of the cited references. It is well established in the patent law, as set forth in, for example, *In re Oetiker*, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) that “[t]he examiner cannot sit mum, leaving the applicant to shoot arrows in the dark hoping to somehow hit a secret objection harbored by the examiner. The ‘prima facie case’ notion, . . . , seemingly was intended to leave no doubt among examiners that they must state clearly and specifically any objections (the prima facie case) to patentability, and give the applicant fair opportunity to meet those objections with

evidence and argument. To that extent the concept serves to level the playing field and reduces the likelihood of administrative arbitrariness.”

The proper question is not whether it would have been obvious to the hypothetical addressee who was presented with an ex post facto selection of prior specifications that elements from them could be combined to produce a new process. It is rather whether it would have been obvious to a non-inventive skilled worker in the field to select from a possibly very large range of publications the particular combination subsequently chosen by the opponent in the glare of hindsight and also whether it would have been obvious to that worker to select the particular combination of integers from those selected publications. In the case of the current combination of claimed process elements, “invention” lies at least in part in the selection of integers, a process which will necessarily involve rejection of other possible integers. The prior existence of publications revealing those integers, as separate items, which *has not* even been established, and other possible integers would not of itself make the present invention obvious. It is the selection of the integers out of, perhaps many possibilities, which must be shown to have been obvious. Moreover, even if one were to combine the base reference with any one or more of the other relied-upon references as set forth in the outstanding Final Office Action, Applicants submit that none of the presently claimed combinations of limitations would be obtained.

Applicants are hopeful that the Examiner can appreciate the need, or at least the benefit and apparent suitability, for additional clarity, and, accordingly, Applicants earnestly request that a new, non-final Office Action be issued specifically elucidating how one of ordinary skill would have considered it to be obvious to **incorporate** the teachings of the Massie et al. method into the method of Bakker et al.

Furthermore, in support of Applicants’ request, the Examiner’s attention is directed to Section 2141 of the MPEP, which advises on what Applicants consider the frequent desirability and appropriateness to “include **explicit** findings as to **how** a person of ordinary skill would have **understood prior art teachings**” (emphasis added).

This same MPEP section continues, stating as follows: “Office personnel must provide an **explanation to support** an obviousness rejection ... 35 U.S.C. 132 requires that the applicant be notified of the **reasons** for the rejection of the claim so that he or she can decide how best to proceed.

**Clearly** setting forth ... the **rationale(s)** to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.”

For the foregoing reasons, Applicants respectfully submit that the Final Office Action is improper, and should be withdrawn.

Applicants request that a new, non-final Office Action be issued, addressing each of the above claim limitations and further addressing each of Applicants’ arguments relating to the above claim limitations, and further establishing a *prima facie* case of obviousness.

Should the Examiner believe that a telephone conference with Applicants’ representative would be helpful to advance the prosecution of the application, or for any other reason, he is kindly invited to contact the undersigned with any such concerns or questions.

The Commissioner is hereby authorized to charge any needed fees to Deposit Account 50-1600.

Respectfully submitted,



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